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particle size range of fentanyl produced, as well as other numerical parameters described in the examples, and any combination thereof.

What is claimed is:

1. A sublingual formulation comprising from about 0.001% to about 15% by weight fentanyl, a free base, or a pharmaceutically acceptable salt thereof, from about 20% to about 60% by weight ethanol, and from about 4% to about 6% by weight propylene glycol, the formulation providing a mean  $T_{max}$  of about 1.28+/-0.60 hours when a dose is administered sublingually to humans.

2. A sublingual formulation comprising from about 0.001% to about 15% by weight fentanyl, a free base, or a pharmaceutically acceptable salt thereof, from about 50% to about 60% by weight ethanol, and from about 4% to about 6% by weight propylene glycol, which provides a plasma concentration after administration to humans selected from the group consisting of: about 60% of the mean  $C_{max}$  in about 10 minutes, about 86% of the mean  $C_{max}$  by about 20 minutes and a combination thereof.

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3. The sublingual formulation of claim 1, that when administered to humans provides a plasma concentration that is greater than about 80% of the mean  $C_{max}$  for about 2 hours.

4. A sublingual spray formulation comprising 400 mcg dose of fentanyl, a free base, or a pharmaceutically acceptable salt thereof, which provides one or more mean pharmacokinetic values selected from the group consisting of:  $AUC_{last}$  4.863+/-1.70821 hr\*ng/mL,  $AUC_{inf}$  5.761+/-1.916 hr\*ng/mL, and  $AUC_{extrap}$  10.26+/-5.66%, when administered to humans.

5. A sublingual spray formulation comprising a dose of fentanyl, a free base, or a pharmaceutically acceptable salt thereof, which provides a substantially dose proportional mean  $AUC_{last}$  based on a mean  $AUC_{last}$  of about 4.863+/-1.70821 hr\*ng/mL for a 400 mcg fentanyl dose when administered to humans.

6. A sublingual spray formulation comprising a 400 mcg dose of fentanyl, a free base, or a pharmaceutically acceptable salt thereof, which provides a mean  $F(AUC_{last})$  of about 0.721+/-0.199 ng/mL when administered to humans.

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